UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,860	05/19/2000	CLAUDINE BRUCK	B45122	6653

20462 7590 03/20/2002

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
JAMROZ, MARGARET E	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 03/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,860	BRUCK ET AL.	
	Examiner	Art Unit	
	Margaret E Jamroz	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/19/2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20 and 22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) ~~Paper No(s).~~ filed 5/19/2000
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction election facsimile* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

2. Applicant's Preliminary Amendment filed 5/19/2000 is acknowledged.
Claims 1-20 and 22 are pending.

3. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

In view of the delays in the mail at the present time, the office strongly encourages faxing responses.

Restriction

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

I. Claims 1-16 and 18-20, drawn a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen, and vaccines comprising a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen and an adjuvant.

II. Claim 17, drawn to an isolated nucleic acid molecule encoding a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen.

III. Claim 22, drawn to a method of treating or preventing allergic responses comprising administering a vaccine comprising a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen.

5. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-III appears to be that they all relate to a recombinant mutant allergen.

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Topham et al. (Protein Engineering 1994; 7(7): 869-894; IDS reference CA) and Smith et al. (Molecular Immunology 1996; 33(4/5): 399-405).

Topham et al. teach a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen (see the Introduction in particular).

Smith et al. teach a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen (see the Introduction and page 403, right column, paragraph 1 in particular).

Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen, and a vaccine comprising a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen and an adjuvant.

The special technical feature of Group II is considered to be an isolated nucleic acid molecule encoding a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen.

The special technical feature of Group III is considered to be a method of treating or preventing allergic responses comprising administering a vaccine comprising a recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature to form a single general inventive concept.

Species Election

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required to elect a specific recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen (e.g. SEQ ID NO: 1) and a vaccine comprising a specific recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen (e.g. SEQ ID NO: 1) and a specific adjuvant (e.g. QS21 OR 3-O-deacylated monophosphoryl lipid A).

These species are distinct because the recombinant mutant allergens differ with respect to their amino acid structure and the adjuvants differ with respect to their structure; thus each specific amino acid sequence encoding a specific mutant allergen in combination with a specific adjuvant represents patentably distinct subject matter. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 12-16 are generic.

If Group II is elected, applicant is required to elect a specific nucleic acid sequence encoding a specific recombinant substantially full-length mutant allergen, wherein said mutant allergen has a reduced enzymatic activity compared to the wild-type allergen.

These species are distinct because the mutant allergens differ with respect to their nucleic acid structure; thus each specific mutant allergen represents patentably distinct subject matter. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

If Group III is elected, applicant is required to elect a specific method of treating or preventing allergic responses comprising administering a specific vaccine comprising a specific recombinant substantially full-length mutant allergen (e.g. SEQ ID NO: 1) and a specific adjuvant (e.g. QS21 OR 3-O-deacylated monophosphoryl lipid A).

These species are distinct because the methods differ with respect to the structure of the specific allergen and specific adjuvant; thus each method employing a specific vaccine comprising a specific mutant allergen and a specific adjuvant represents patentably distinct subject matter. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
March 18, 2002

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640